MAY 1 1 2005

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K051100

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Contact: Mr. Gerhard Frick

Date Summary Prepared: April 27, 2005

2. Name of the Device:

Microlife Digital pacifier Thermometer, Model MT1751Q

3. Predicate Device Information:

Pro Check ™ Digital Pacifier Thermometer, K#972259, Micro Weiss Electronics

4. Device Description:

The Microlife Digital Pacifier Thermometer, Model MT1751Q, is a battery-powered, liquid crystal display device using a thermistor inside the nipple. The patient contact portion is composed of medical silicone rubber. The body is of ABS plastic. This device is reusable and no components are disposable.

In addition, to speed up the measurement time, we have added the fixed offset into this thermometer, which is fulfilled by the hardware. With these characteristics, this thermometer can provide both a very high clinical accuracy and quick measurement time.

The basic principle of this thermometer is that change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of R-C oscillator circuit, Therefore, temperature can be given by measuring the frequency of the oscillator.

5. Intended Use:

The Microlife MT1751Q Digital Pacifier Thermometer is a non-sterile, reusable clinical thermometer intended for the determination of oral body temperature in infants to children five years of age.

6. Comparison to Predicate Devices:

The Microlife Digital Pacifier Thermometer, Model MT1751Q, is identical to the Pro Check ™ Digital Pacifier Thermometer,K#972259, differing mostly in response time and, the position of the thermistor is fixed .

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the Microlife Digital Pacifier Thermometer, Model MT1751Q. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. Conclusions:

The Microlife Digital Pacifier Thermometer, Model MT1751Q, has the same intended use and similar technological characteristics as the predicate device, the Pro Check ™ Digital Pacifier Thermometer, K#972259. Moreover, bench testing contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Digital Pacifier Thermometer, Model MT1751Q, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K051100
Trade/Device Name: Microlife MT1751Q Digital Pacifier Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2005
Received: April 29, 2005

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051100 1 OF

Exhibit B

510(k) Number (if known): K051100

Device Name: Microlife MT1751Q Digital Pacifier Thermometer

Indications For Use:

The Microlife MT1751Q Digital Pacifier Thermometer is a non-sterile, reusable clinical thermometer intended for the determination of oral body temperature in infants to children five years of age.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use _X_
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051100